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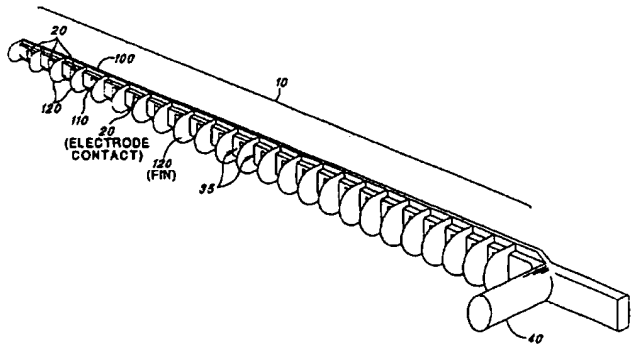

(57) Abstract

An electrode array (10) for stimulation of the cochlea includes an elongated tapered carrier (15) on which a multiplicity of separately controlled electrode contacts (20) are carried. A set of flexible fins (100, 110, 120) extend from the carrier in particular axes so as to cause the outside dimension of the array plus the fins to be greater than the typical cross section of the cavity in which the array is to be inserted. The fins are made from compliant, dielectric material so that they can be folded against the body of the carrier as it is inserted into the cochlea so that they slide past obstructions and accommodate variations in the cross-sectional dimensions of the cavity, e.g., the scala tympani (5). When in place; the fins unfurl so that they touch the walls of the cavity into which they are inserted, thereby forming a series of separate longitudinal compartments (35), at least most of which contain at least one separate stimulating electrode. The fins confine electrical currents injected through most of the contacts to flow preferentially through different portions of the wall of the cavity in which the electrode array is inserted, thereby selectively stimulating/activating cells encompassed by the compartments.

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COCHLEAR ELECTRODE ARRAY EMPLOYING DIELECTRIC PARTITIONS

Background of the Invention

The present invention relates to implantable stimulation devices, e.g., cochlear prothesis used to electrically stimulate the auditory nerve, and more particularly to an electrode array employing dielectric partitions that may be used with such implantable stimulating devices.

A cochlear prosthesis provides sensations of sound for patients suffering from sensorineural deafness. It operates by direct electrical stimulation of the auditory nerve cells, bypassing the defective cochlear hair cells that normally transduce acoustic energy into electrical activity in such nerve cells. In addition to stimulating the nerve cells, the electronic circuitry and the electrode array of the cochlear prosthesis must perform the function of the separating the acoustic signal into a number of parallel channels of information, each representing the intensity of a narrow band of frequencies within the acoustic spectrum. Ideally, each channel of information would be conveyed selectively to the subset of auditory nerve cells that normally transmitted information about that frequency band to the brain. Those nerve cells are arranged in an orderly tonotopic sequence, from high frequencies at the basal end of the cochlear spiral to progressively lower frequencies towards the apex. In practice, this goal tends to be difficult to realize because of the anatomy of the cochlea.

After extensive research in many centers employing a variety of surgical sites and approaches for the implantation of cochlear electrode arrays, a consensus has generally emerged on the use of the scala tympani, one of the three parallel ducts that, in parallel, make up the spiral-shaped cochlea. The electrode array to be implanted in this site typically consists of a thin, elongated, flexible carrier containing several longitudinally disposed and separately connected stimulating electrode contacts, perhaps 6-24 in number. Such electrode array is pushed into the scala tympani duct to a depth of about 20-30 mm via a surgical

opening made in the round window at the basal end of the duct. During use, electrical current is passed into the fluids and tissues immediately surrounding the individual electrical contacts in order to create transient potential gradients that, if sufficiently strong, cause the nearby auditory nerve fibers to generate action potentials. The auditory nerve fibers arise from cell bodies located in the spiral ganglion, which lies in the bone adjacent to the scala tympani on the inside wall of its spiral course. Because the density of electrical current flowing through volume conductors such as tissues and fluids tends to be highest near the electrode contact that is the source of such current, stimulation at one contact site tends to activate selectively those spiral ganglion cells and their auditory nerve fibers that are closest to that contact site.

The selectivity of stimulation at each site provides a means for conveying different sound perceptions. Typically, cells (and their corresponding auditory nerve fibers) that are in one region or area convey sound perceptions within a given frequency band or channel. This selectivity of stimulation at each site provides a lower limit on the useful spacing available between adjacent sites. That is, if adjacent sites closer than that lower-limit spacing are stimulated simultaneously, then the signals carried by the neurons can no longer distinguish respective frequency bands separately, but rather will convey signals that are contaminated by cross-talk between channels and may be perceived as unclear and/or excessively loud. This lower-limit spacing also effectively limits the maximal number of parallel channels of information that can be conveyed about acoustic signals such as speech because the length of the scala tympani over which the complete range of speech signal frequencies is represented is fixed at about 15-20 mm in length. Further, the actual selectivity of stimulation at each site is limited by the spreading of the injected electrical current through the volume-conductive tissues and fluids of the cochlea.

Several stimulation strategies have been described in the prior art for maximizing the selectivity. These include:

Bipolar Stimulation - Bipolar stimulation provides two closely spaced electrode contacts within the scala tympani which are used to provide both a source and sink for the stimulating electrical current (see e.g., U.S. Patent No. 4,819,647), instead of the monopolar configuration in which the sink for all channels is a common electrode located outside of the cochlea. With bipolar stimulation, the rate at which the current density decreases with distance from the electrodes is much greater than with monopolar stimulation. There is a significant disadvantage, however, in that the amount of current required to produce adequate stimulation at each site and the power required to pass that current through the tissues is much higher than for monopolar stimulation. This is a significant disadvantage for the efficient design and operation of implanted microminiature circuitry in a portable battery-powered system.

Directional Contacts - In some electrode designs, the individual contacts are shaped like cigar bands, causing the stimulating current to radiate in all directions equally. By using smaller contacts that occupy only a portion of the transverse cross-section of the electrode carrier at a particular longitudinal position, the current density can be made asymmetrical (see, e.g., U.S. Patent Nos. 4,686,765; 4,819,647). If the design of the electrode array and its placement by the surgeon permits the contacts to be reliably positioned so as to be facing the medial wall of the scala tympani, in which the spiral ganglion cells reside, the selectivity will be somewhat improved. The improvement tends to be limited, however, by the tendency of stimulating current to disperse broadly through the relatively conductive fluids of the scala tympani. Furthermore, the small surface area of the contacts will increase their electrical impedance and, hence, the voltage required to deliver a particular stimulating current.

Spiral-Shaped Carriers - Regardless of the design of the electrode contacts and the tissues in which they reside, the current density is always

highest nearest the contact surface. One strategy, therefore, that has been used with small contacts that face the medial wall is to embed them in an elastomeric carrier that is molded into the shape of the cochlear spiral (see U.S. Patent Nos. 4,686,765; 4,819,647). Upon insertion, the carrier regains its spiral shape, drawing the contacts close to the medial wall. The fabrication of such an electrode array is somewhat complicated, however. Furthermore, special instruments and techniques must be used by the surgeon in order to hold the electrode straight in order to effect insertion into the round window opening.

Space-Filling Carriers - Yet another technique known in the art to position directional contacts near the medial wall is to make the electrode array relatively thick in cross-section. This can be done by using a mold whose dimensions are sized closely to the cross-sectional dimensions of the scala tympani (see U.S. Patent Nos. 4,686,765; 4,819,647). Other techniques that achieve this same purpose could include adding flexible fins along the lateral edge to push the electrode towards the medial wall, or by making some or all of the carrier from a material that swells, inflates, or otherwise changes its dimensions after insertion. One problem with these techniques is that there is a fairly large range of variability in the dimensions of the scala tympani from one patient to another and there are often irregularities in cross-sectional area along the length of an individual scala tympani. As the electrode contacts get closer to the medial wall, even small fluctuations in the actual gap and the points of actual contact with the side walls can cause large changes in the distribution of the stimulating currents from each site, which may disrupt the orderly tonotopic representation and the balance of loudness between channels. Furthermore, the surgeon who performs the implant generally prefers an electrode that is as thin as possible to improve the chances of being able to insert it successfully in any conditions that may obtain.

Separate Contact Placements - Another technique for maximizing the selectivity of stimulation sites is to drill into the scala tympani through its lateral wall at multiple locations and place a separate stimulating electrode in each site, as described by Chouard and MacLeod (1976). Before sealing the holes, small plugs of a nonconductive material such as silicone elastomer are inserted into the holes so as to flank each electrode in an attempt to prevent its currents from spreading longitudinally in the conductive fluid of the scala tympani. Several problems developed with this technique that caused it to be abandoned. Only one side of the cochlear spiral is surgically accessible in this manner and even then, it is difficult to perform the multiple fenestrations without damaging the extremely delicate membranes that separate the three parallel canals. Further, even if accurately-sized plugs could be installed, they tend to block only longitudinal conduction and not lateral conduction out of the scala tympani and into adjacent, overlying turns of the spiral; in fact, the scar tissue that eventually seals over the fenestrations tends to be more conductive than the bone that it replaces, actually channeling stimulation currents laterally rather than in the desired medial direction.

Summary of the Invention

The cochlear electrode array that is the subject of the present invention includes a single elongated, tapered carrier on which a multiplicity of electrode contacts are carried. The electrode array is designed to be inserted into the scala tympani via an opening at or near the round window, in the conventional manner. A set of thin fins project from the body of the carrier in particular axes. These fins are made of a highly flexible but resilient material that can be folded against the body of the carrier so as to slide past obstructions and to accommodate variations in the cross-sectional dimensions of the scala tympani.

In a preferred embodiment, the flexible fins are extensions of the silicone elastomer that forms the body of the carrier and are molded as one with the body of the carrier in a single injection molding process. In other embodiments, the fins may be formed or added to the carrier employing a variety of other materials and processes known in the art.

In accordance with one aspect of the invention, the fins should be made of a dielectric material, i.e. a material with a much higher resistivity to electrical current than any of the surrounding tissues of the cochlea. Upon insertion, the elastic fins are designed to unfurl so that they touch the walls of the scala tympani, effectively separating it into a series of separate longitudinal compartments, each of which contains a separate stimulating electrode. Because the fins have a much higher resistivity than the surrounding tissue, current can flow to or from the electrode in each compartment only through the portion of the wall of the scala tympani that lies within that compartment, thereby enhancing the selectivity of the spiral ganglion cells adjacent to that compartment.

It is a feature of the invention to provide a cochlear electrode array that produces a predictable and highly selective activation of spiral ganglion cells at each of a large number of closely spaced sites along the longitudinal axis of the cochlea.

It is a further feature of the invention to provide a cochlear electrode array that is readily insertable in scalae tympani that have a wide range of dimensions and even partial obstructions.

It is another feature of the invention to provide a cochlear electrode array that has a minimal likelihood of producing damage to the cochlea upon its initial insertion, after prolonged function, and even in the event that surgical removal and/or replacement is required.

It is yet an additional feature of the invention to provide a cochlear electrode array that minimizes the electrical power required to achieve adequate stimulation and perceived loudness.

It is still another feature of the invention to provide a cochlear electrode array that is readily manufacturable.

Brief Description of the Drawings

The above and other aspects, features and advantages of the present invention will be more apparent from the following more particular description thereof, presented in conjunction with the following drawings, wherein:

FIG. 1 shows a perspective view of an electrode array made in accordance with one embodiment of the present invention;

FIG. 2A is a top schematic representation of the electrode array of FIG. 1;

FIG. 2B is an expanded top view of one of the compartments of the electrode array;

FIG. 2C is an expanded front view of one of the compartments of the electrode array;

FIG. 3A is a cross-sectional view taken along the line A-A in FIG. 2A;

FIG. 3B is a cross-sectional view taken along the line B-B in FIG. 2A;

FIG. 3C is a cross-sectional view taken along the line C-C in FIG. 2A;

FIG. 3D shows the desired fit of the apical cross-section A-A in the scala tympani; and

FIG. 4 shows a cross-sectional view of an alternative embodiment of the invention that includes an additional elongated electrode contact that may be used as a reference or return electrode.

Corresponding reference characters indicate corresponding components throughout the several views of the drawings.

Detailed Description of the Invention

The following description is of the best mode presently contemplated for carrying out the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be determined with reference to the claims.

An example of a prior electrode array, and the manner of making such an array, is taught in United States Patent Nos. 4,686,765 and 4,819,647, both of which are incorporated herein by reference.. Many of the teachings of these patents, e.g., regarding physiology of the cochlea, materials for the electrodes and carrier/body, manufacturing techniques, sizes, dimensions of the scala tympani, etc., apply equally well to the present invention.

A preferred embodiment of an electrode array 10 made in accordance with the invention is shown in FIGS 1, 2A, 2B, and 2C. FIG. 1 shows a perspective view of the electrode array 10; FIG. 2A is a top schematic representation of the electrode array 10; FIG. 2B is an expanded top view of one small section or compartment 35 of the electrode array 10; and FIG. 2C is an expanded front view of one of the compartments 35 of the electrode array.

As seen in FIGS. 1, 2A, 2B and 2C, the electrode array 10 includes a body 15, a multiplicity of individual contacts 20 and their associated wire leads 30 coursing through the body 15, plus fins 100, 110, and 120. The outside dimensions of the electrode array plus fins at various points along the length of the array is carefully sized so as to be at least slightly larger than available cross-sectional dimensions of the scala tympani in most human beings. Typical cross-sectional profiles at three points along the array, designated A-A, B-B and C-C in FIG 2A, are shown in FIGS 3A, 3B and 3C, respectively.

After insertion of such an electrode 10 to the intended depth in the scala tympani, the various fins will touch and be somewhat bent or compressed by

their contact with the walls of the scala tympani. The desired fit of the apical cross-section A-A in the scala tympani is shown in FIG. 3B.

In the preferred embodiment that is illustrated in the figures, the fins lie in only two axes. One pair of fins 100 and 110 projects perpendicularly from the body so as to create a longitudinal barrier in the vertical axis of the spiral. It is a feature of this arrangement that any stiffness contributed by fins 100 and 110 contributes to the desired property of the electrode array that it flex readily in only this vertical axis, particularly in the more apical regions of the scala tympani where the electrode array must curl tightly along this axis to conform to the spiral shape of the cochlea. This flexion property is further enhanced in the preferred embodiment by the gathering of leads 30 into a vertically aligned "rib" 35 as illustrated in the cross-sectional view in FIG 3B.

A multiplicity of fins 120 project perpendicularly from body 15 in the medial direction of the transverse plane, lying orthogonal to and joining with fins 100 and 110. Transverse fins 120 effectively divide the scala tympani 5 (seen in FIG. 3D) into a set of longitudinally separate compartments 35 (FIGS. 2A, 2B) within each of which there is one individual electrode contact 20. When all of the various fins have unfurled so as to touch the walls of the scala tympani as shown in FIG 3D, the electrical current injected from each contact must pass through the bone that forms the medial wall 3 (FIG. 3D) of each separate compartment, and thence into the subjacent portion of the spiral ganglion 6. Thus, all or most of the stimulating current delivered to a given contact tends to be directed to, and hence flow through, the spiral ganglion, where it can effectively stimulate the auditory neurons 7, rather than being dissipated in other paths that do not intersect these neurons.

Also shown in FIG. 3D is an elongated electrode contact 50 that is inserted into the scala vestibuli 8 so as to provide a return pathway for stimulation current injected into the cochlea from one or more individual contacts 20. Elongated electrode contact 50 lies parallel to all or much of the length of electrode

array 10. This arrangement further enhances the tendency of stimulation currents to flow parallel to spiral ganglion neuron 7 stimulating them efficiently and selectively.

It should be appreciated that transverse fins 120 add little or no stiffness to the electrode array 10 in the axis along which the array must flex to accommodate the cochlear spiral. Furthermore, the transverse fins can be bent or furled in either longitudinal direction so that the electrode array can slide out of the scala tympani even if connective tissue grows into some or all of the various compartments 35 created between the fins. A tab 40 (FIG. 2A) projecting from the array at its basal end can be used as a handle whereby the surgeon pushes or pulls the electrode array to effect insertion or removal of the electrode array. The tab 40 also provides a marker indicating that the electrode array has been inserted to the intended depth when the tab 40 is aligned with the round window opening.

In another embodiment of the invention shown in FIG. 4, an elongated electrode contact 50 is added to the lateral surface of body 15 along all or most of the length of the array (e.g., along the back side of the array in the region between sectional lines A and C of FIG. 2A). This elongated electrode contact 50 may be used as the return electrode for some or all of the stimulating pulses applied to individual contacts 20. As described in a separate patent application of the inventor, Serial No. 08/516,758, filed 08/18/95, which application is incorporated herein by reference, this arrangement causes each site of stimulation to behave in a quasi-bipolar mode, further reducing any tendency for stimulation current to spread longitudinally. This arrangement also increases the tendency for the current (designated "i" in FIG. 4) flowing through the spiral ganglion to follow a course that lies parallel to the elongated processes of neurons 7, which is more efficient for activating those neurons.

The electrode contacts 20 and 50, if present, may be made of any biocompatible electrode material such as platinum and its alloys, iridium or anodized tantalum. The associated electrode leads 30 may be made of any similarly

biocompatible conductive material. The mechanical properties, shape and dimensions of leads 30 and their disposition within body 15 can be used to modify the flexibility and other handling properties of the electrode array 10 so as to improve its insertability into the scala tympani. For example, it may be advantageous to use one or more different calibers of individual round or flattened wires with various of the apical or basal contacts, or to use a ribbon cable in which a multiplicity of wires are held together by bonds or envelopments of dielectric material.

Alternatively or additionally, some or all of body 15 may be fabricated from a stiffer material than the material used for fins 100, 110 and 120. This can be accomplished. for example, by molding body 15 as a preform from a silicone elastomer having a relatively high duramater value and then inserting this preform into the mold used to add fins made from a lower duramater elastomer. (Note: the "duramater" is the tough, fibrous membrane forming the outermost of the three coverings of the brain. Thus, as used here, a relatively high duramater value means a toughness that is relatively high compared to the toughness of the duramater.) It may be advantageous for the preform to contain various wells, pockets or other shape features to facilitate the placement of contacts 20 and leads 30 during fabrication of electrode array 10.

It is desirable for the electrode array 10 to be relatively stiff in all directions at the basal end of the electrode array 10, a cross-sectional view of which basal end is shown in FIG. 3C. In order to achieve this, the relatively large number of electrode leads 30 present at this point are dispersed throughout the relatively thick body 15 rather than gathering into a rib 35 as illustrated in FIG 3B.

While the invention herein disclosed has been described by means of specific embodiments and applications thereof, numerous modifications and variations could be made thereto by those skilled in the art without departing from the scope of the invention set forth in the claims.

CLAIMS

1. An electrode array (10) for insertion into a body cavity for nerve stimulation comprising:

a flexible body (15);

a multiplicity of separately-controlled, spaced-apart, electrode contacts (20) carried by said body; and

fins (100, 110, 120) made from a compliant, dielectric material and projecting from said body so as to cause the outside dimension of said array plus said fins to be equal to or greater than the typical cross-section of the cavity in which said array is to be inserted.

2. The electrode array of Claim 1 wherein the body cavity in which the electrode array is inserted comprises the scala tympani (5) of the cochlea, and wherein the electrode array is adapted to selectively stimulate neurons of the auditory nerve.

3. The electrode array of Claims 1 or 2 wherein the number of electrode contacts comprises at least six, and wherein at least one fin resides on each side of each electrode contact except for an end electrode contact.

4. The electrode array of Claims 1, 2 or 3 wherein said fins comprise orthogonal fins lying in two axes; a first set of fins projecting substantially perpendicularly from the longitudinal axis of the flexible body so as to create a longitudinal barrier in a vertical axis; and a second set of fins, generally orthogonal to and joining the first set of fins, that project substantially perpendicularly from the body in a medial direction of a transverse plane; said fins effectively dividing the cavity into which the electrode array is inserted into a set of longitudinally separate compartments, within at least most of which resides one of said electrode contacts.

5. The electrode array of Claim 1 wherein the flexible body is made from a material that is stiffer than the material from which said fins are made.

6. The electrode array of Claim 2 wherein each of the multiplicity of electrode contacts includes a separate wire (30) through which electrical contact may be made with the respective electrode contact, each of the wires of the multiplicity of electrode contacts being embedded within the flexible body.

7. The electrode array of Claim 6 wherein the wires within the flexible body are gathered to form a rib in at least those regions of the electrode array between its tip and midpoint.

8. The electrode array of Claim 6 wherein the wires within the flexible body are dispersed throughout the flexible body in that region of the electrode array near its basal end.

9. The electrode array of Claims 2, 3 or 4 further including an elongated electrode contact (50) insertable into the scala vestibuli so as to provide a return pathway for stimulation current injected into the cochlear from one or more of said electrode contacts (20).

10. An electrode array (10) for insertion into and stimulation of the cochlea comprising:

a multiplicity of separately controlled electrode contacts (20), and

fins (100, 110, 120) made from a compliant, dielectric material that cause electrical currents injected through most of said contacts to flow preferentially through different portions of the wall of the cavity in which said array is to be inserted.

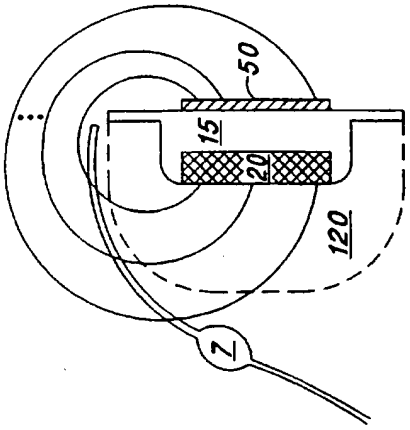
50
15
20
120
7

FIG. 4

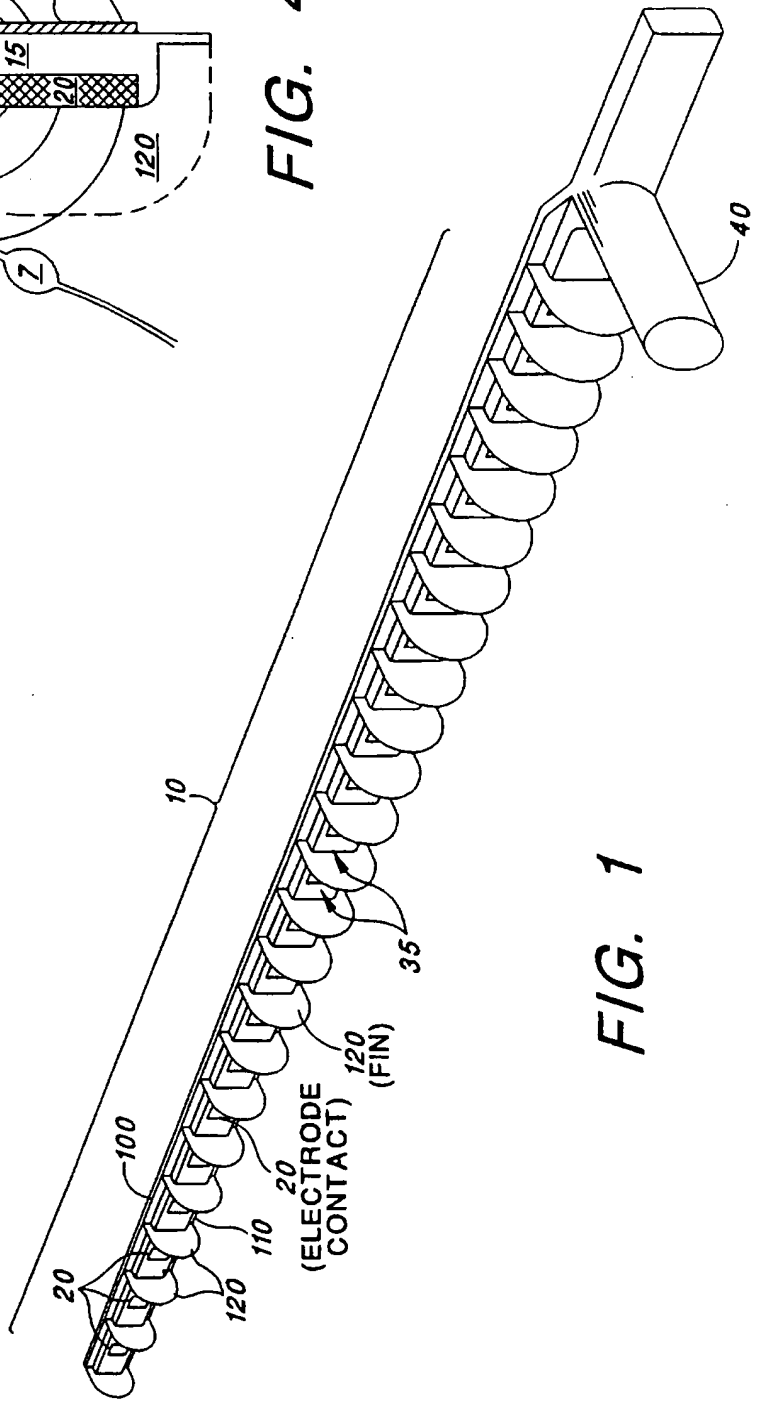
40
10
35
120
(FIN)
20
(ELECTRODE
CONTACT)
100
110
120
20

FIG. 1

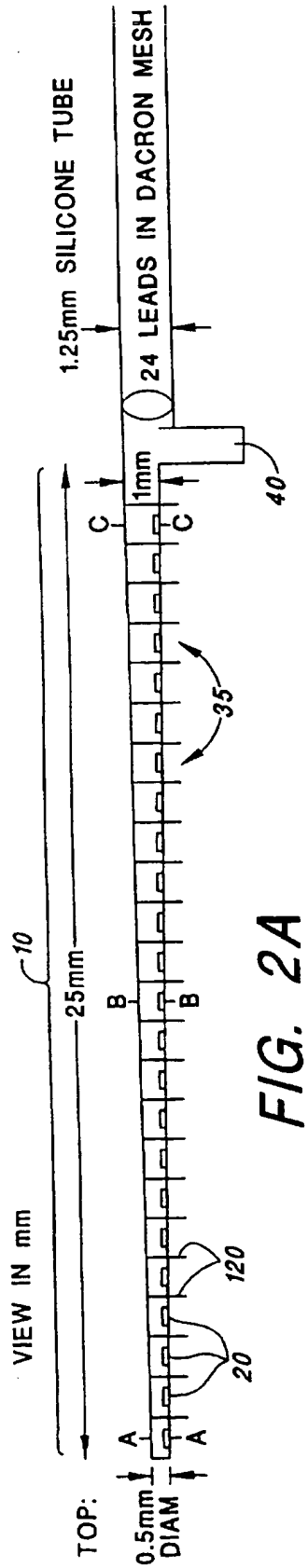

FIG. 2A

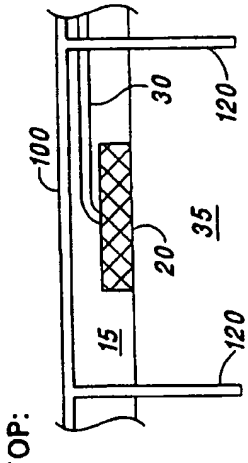

FIG. 2B

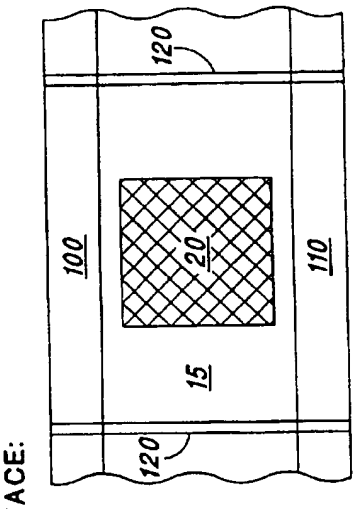

FIG. 2C

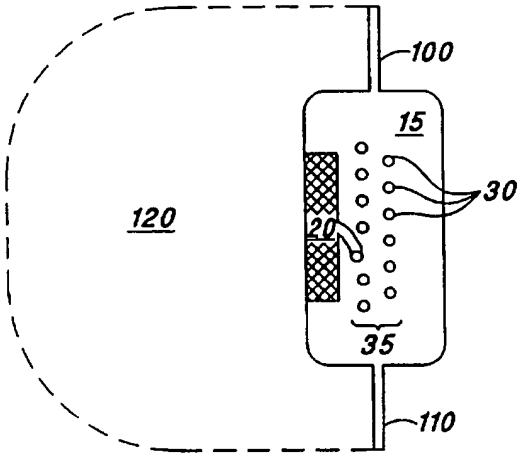

FIG. 3B

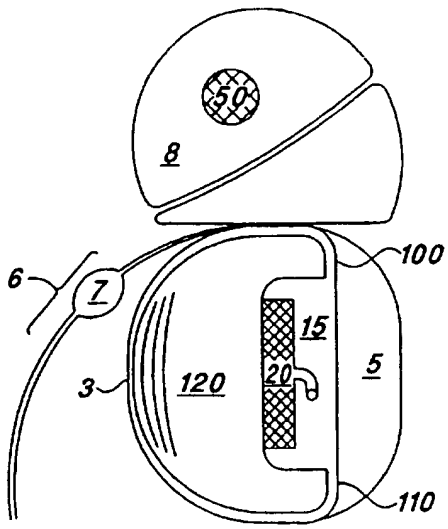

FIG. 3D

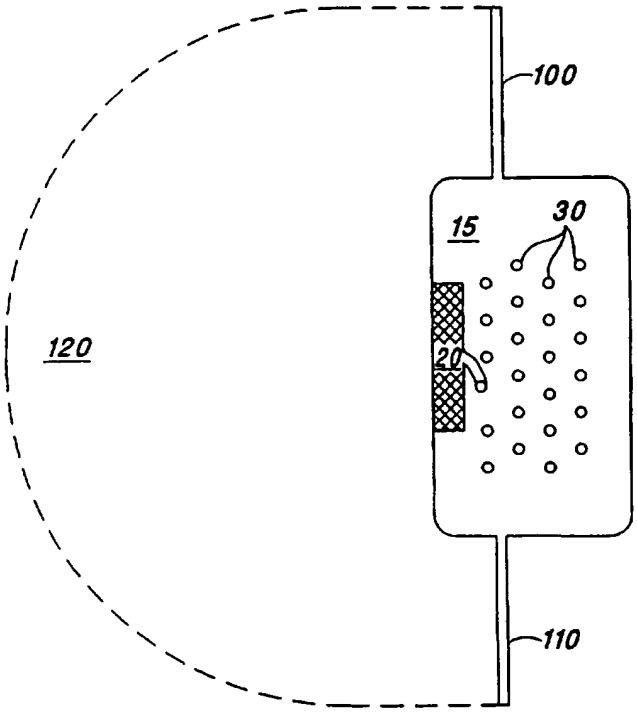

FIG. 3C

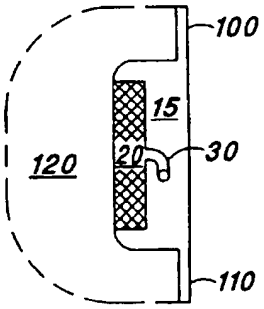

FIG. 3A

INTERNATIONAL SEARCH REPORT

Inte[illegible]onal Applicat[illegible]
PCT/US 97/00[illegible]

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/36 A61F11/04 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 93 06698 A (COCHLEAR PTY) 1 April 1993 see the whole document ---	1,10
A	US 4 832 051 A (JARVIK) 23 May 1989 see the whole document -----	1,10

☐ Further documents are listed in the continuation of box C.

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15 May 1997	22.05.97

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. nal Application No
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